Notice of Allowability	Application No.	Applicant(s)	
	09/785,514	FAN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *24 October 2006*.

2. ☒ The allowed claim(s) is/are *21,22,24,26-29,36,38 and 39*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 10/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

BJ Forman
Primary Examiner
Art Unit: 1634

NOTICE OF ALLOWANCE

Status of the Claims

This action is in response to papers filed 24 October 2006 in which a Terminal Disclaimer was submitted, claims 24, 26-29 and 38 were amended, claims 14-20, 23, 25, 30-35 and 37 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 14 September 2006 are withdrawn in view of the amendments and Terminal Disclaimer. The amendments and Terminal Disclaimer place the pending claims in condition for allowance.

A complete and correct listing of the claims is attached hereto.

Claims 21-22, 24, 26-29, 36 and 38-39 are in condition for allowance.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claims 21-22, 24, 26-29, 36 and 38-39 have been renumbered Claims 1-10 according to 37 C.F.R. 1.126 (see MPEP 608.01 (j) and 608.01 (n) IV).

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The claims are drawn to methods of genotyping and/or nucleotide identification. The methods require first and

second target nucleic acid molecules from two individuals attached to microspheres wherein at least a first and second different target nucleic acids are attached to each microsphere.

The instant specification defines a target as a molecule in a sample that is to be detected. Furthermore, the instant claims define the differing target nucleic acids as from different individuals. Hence, the instantly claimed targets are distinguished from non-sample nucleic acids such as probes, primers, oligo-tags. The prior art does not teach or reasonably suggest an array composition comprising target molecules from two individuals covalently attached to microspheres as claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Listing of Claims:

Claims 1- 20 (cancelled).

21. (previously presented) A method of genotyping comprising:

a) providing an array composition comprising:

i) a substrate with a surface comprising discrete sites; and

ii) a population of microspheres comprising at least a first and a second subpopulation, wherein the microspheres of said first subpopulation comprise at least first and second different target nucleic acid molecules from a first individual and the microspheres of said second subpopulation comprise at least first and second different target nucleic acid molecules from a second individual, wherein said at least first and second different target nucleic acid molecules are covalently attached to each of said microspheres with first and second attachment moieties, respectively;

wherein said microspheres are randomly distributed on said surface;

b) contacting said array composition with a first set of extension probes that hybridize with at least said first target nucleic acid molecules adjacent to a first detection position to form an extension complex;

c) contacting said extension complex with a composition comprising

i) at least a first nucleotide;

ii) polymerase;

wherein said polymerase extends a first extension probe with said first nucleotide when said first nucleotide is complementary to said first detection position; and

d) detecting the presence of said first nucleotide, whereby said genotype is determined.

22. (original) The method according to claim 21, wherein said first nucleotide comprises a label.

Claim 23 (cancelled).

24. (currently amended) ~~The method according to claim 23,~~ A method of determining the identification of a nucleotide at a detection position in at least a first target nucleic acid molecule comprising:

a) providing an array composition comprising:

i) a substrate with a surface comprising discrete sites; and

ii) a population of microspheres comprising at least a first and a second subpopulation, wherein the microspheres of said first subpopulation comprise a plurality of different target nucleic acid molecules from a first individual and the

microspheres of said second subpopulation comprise a plurality of different target nucleic acid molecules from a second individual, and wherein a plurality of said different target nucleic acid molecules are covalently attached to each of said microspheres, wherein said microspheres are distributed on said surface;

b) forming a first hybridization complex between said first target nucleic acid molecule and at least a first readout probe, wherein said first target nucleic acid molecule comprises a first and a second target domain, wherein said first hybridization complex comprises said first target nucleic acid molecule, a first readout probe hybridized to said first domain and a second readout probe hybridized to said second domain, wherein at least one of said readout probes comprise a label said determining comprises adding a ligase to form a ligation complex, and

c) determining the nucleotide at said detection position.

Claim 25 (cancelled).

26. (currently amended) ~~The method according to claim 23, further comprising~~ A method of determining the identification of a nucleotide at a detection position in at least a first target nucleic acid molecule comprising:

a) providing an array composition comprising:

i) a substrate with a surface comprising discrete sites; and

ii) a population of microspheres comprising at least a first and a second subpopulation, wherein the microspheres of said first subpopulation comprise a plurality of different target nucleic acid molecules from a first individual and the microspheres of said second subpopulation comprise a plurality of different target nucleic acid molecules from a second individual, and wherein a plurality of said different target nucleic acid molecules are covalently attached to each of said microspheres, wherein said microspheres are distributed on said surface;

b) forming a first hybridization complex between said first target nucleic acid molecule and at least a first readout probe;

c) contacting said hybridization complex with at least a first nucleotide and a polymerase, wherein said polymerase extends said first readout probe with said first nucleotide when said first nucleotide is complementary to said first detection position, and

d) determining the nucleotide at said detection position.

27. (currently amended) The method according to claims ~~14,~~ 21, 24 or 26 ~~or 23~~ wherein said substrate is a fiber optic bundle.

28. (currently amended) The method according to claim s ~~14,~~ 21, 24 or 26 ~~or 23~~ wherein said substrate is selected from the group consisting of glass and plastic.

29. (currently amended) The method according to claim s ~~14,~~ 21, 24 or 26 ~~or 23~~ further comprising contacting said microspheres with decoder binding ligands, wherein the microspheres of each subpopulation comprises an identifier binding ligand that will bind a decoder binding ligand for identification and elucidation of said target analyte.

Claims 30-35 (cancelled).

36. (previously presented) A method of genotyping comprising:

a) providing an array composition comprising:

i) a substrate with a surface comprising discrete sites; and

ii) a population of microspheres comprising at least a first and a second subpopulation, wherein the microspheres of said first subpopulation comprise at least first and second different target nucleic acid molecules from a first individual and the microspheres of said second subpopulation comprise at least first and second different target nucleic acid molecules from a second individual, wherein said plurality of first and second different target nucleic acid molecules are attached to each of said microspheres via receptor-ligand interaction; wherein said target analytes are derivatized with said receptor or said ligand,

wherein said microspheres are randomly distributed on said surface;

b) contacting said array composition with a first set of extension probes that hybridize with at least said first target nucleic acid molecule adjacent to a first detection position to form an extension complex;

c) contacting said extension complex with a composition comprising

i) at least a first nucleotide;

ii) polymerase;

wherein said polymerase extends a first extension probe with said first nucleotide when said first nucleotide is complementary to said first detection position; and

d) detecting the presence of said first nucleotide, whereby said genotype is determined.

Claim 37 (cancelled).

38. (currently amended) The method according to claim ~~35,~~ 36 ~~or 37~~, wherein said receptor is streptavidin and said ligand is biotin.

39. (previously presented) The method according to claim 38, wherein said microspheres are streptavidin coated.

Conclusion

Claims 21-22, 24, 26-29, 36 and 38-39 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Art Unit: 1634
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